K082125

Summary Of Safety And Effectiveness

NOV 21 2008

A. Information

1. Submitter's

Name:	Best Glove, Inc.
Address:	579 Edison Street Menlo, GA 30731-6335
Telephone Number:	706-862-6712
Contact person:	Neil Dow

2. Name of Device

Trade or Proprietary name:	Nitrile Powder-Free Medical Examination Glove (Black).
Common or Usual name:	Non-sterile Powder-Free Patient Examination glove.
Classification Name:	Patient Examination Glove (80LZA, 21 CFR 880.6250)

3. Predicate Device: Nitrile Powder-Free medical Examination Glove (green)

   Submission Number: K012899

4. Description Of Device

   The N-DEX® NightHawk® Black Nitrile Powder-Free Medical Examination Glove is a disposable device intended for medical purposes; that is worn on the examiner's hand, to prevent contamination between the patient and examiner.

5. Statement of intended use, including descriptions of the disease or conditions that the device will address:

   This is a disposable device intended for medical purposes that is worn on the examiners hands to prevent contamination between the patient and the examiner. Powder-Free examination gloves are suitable in situations where powder is not desirable.

6. Explanation of similarities or differences to predicate device

   The proposed device is identical to the predicate device except for the following:

   The proposed device has been rendered black instead of green.

B. If SE decision is based on performance:

1. Non-Clinical Tests

Specification	Predicate Device	Proposed Device
	Nitrile Powder-Free Medical Examination Glove (green)	Nitrile Powder-Free Medical Examination Glove (black)
Performance standards (conforms)	ASTM D 6319-00a ASTM D 6124-01	ASTM D 6319-00a ASTM D 6124-06
Water tightness (conforms)	ASTM D 5151-99	ASTM D 5151-06

2. Clinical Tests (Animal Studies)

Biocompatibility	Predicate Device	Proposed Device
ISO Skin Irritation Study (ISO 10993-10)	Passes	Passes
ISO Closed Patch Sensitization Study (ISO 10993-10)	Passes	Passes
Cytotoxicity Study (ISO 10993-5)	Not tested	Passes

REPORTS OF SAFETY OR EFFECTIVENSS DATA OBTAINED
(With specific reference to adverse effects and complications)

See Section J: Biocompatibility Testing.

CONCLUSIONS DRAWN FROM NON CLINICAL AND CLINICAL TESTS THAT DEMONSTRATE SAFETY AND EFFECTIVENESS, AND PERFORMANCE EQUAL TO OR BETTER THAN THE PREDICATE PRODUCT

The Nitrile Powder-Free Medical Examination Glove (black) has been carefully compared to a legally marketed device in the 510(k). The data summaries indicate that the proposed product meets or exceeds accepted scores for the predicate product in both physical and nonclinical tests and satisfies the requirements for a safe and effective powder-free medical glove.

Pursuant to 21 C.F.R. 807.87 (k), I, Neil Dow, Regulatory Affairs and Quality Assurance Manager, certify that to the best of my knowledge and belief, and based upon the data and information submitted to me in the course of my responsibilities as Regulatory Affairs and Quality Assurance Manager for Best Glove, Inc, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Neil Dow

Neil Dow
Regulatory Affairs and Quality Assurance Manager

24 Sep 2008

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Neil Dow
Regulatory Affairs & Quality Assurance Manager
Best Glove, Incorporated
579 Edison Street
Menlo, Georgia 30731-6335
United States

NOV 21 2008

Re: K082125
Trade/Device Name: N-DEX® NightHawk® Black Nitrile Powder-Free Medical Examination Glove, Non-Sterile
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: September 30, 2008
Received: October 20, 2008

Dear Mr. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: N-DEX® NightHawk® Black Nitrile Powder-Free Medical Examination Glove, Non-Sterile

Indications For Use:

The N-DEX® NightHawk® Black Nitrile Powder-Free Medical Examination Glove is a disposable device intended for medical purposes; that is worn on the examiner's hand, to prevent contamination between the patient and examiner (21 CFR 880.6250).

Prescription Use _____ AND/OR Over-The-Counter Use __x__
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082125